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PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of

David H. REIFSNYDER *et al.*

Serial No.: 10/753,078

Filed: January 8, 2004

)  
) Group Art Unit: 1656

) Examiner: Schnizer, Holly G.

) Atty. Dkt. No.: 012441.00050

) (PP-16331.004)

For: IMPROVED METHOD OF PURIFYING TFPI AND TFPI ANALOGS

**SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT**

U.S. Patent and Trademark Office  
Randolph Building  
Customer Service Window  
401 Dulany Street  
Alexandria, VA 22314

Sir:

In accordance with 37 C.F.R. §§ 1.97 and 1.98, attached are Forms PTO/SB/08 a and b citing references, in addition to the those previously cited in the Information Disclosure Statement submitted on January 10, 2005, for consideration by the Examiner during prosecution in the above-captioned patent application. Applicants respectfully request that the Examiner consider and enter the cited references into the file of the above-captioned patent application. Applicants also request an indication of the same by return of the Form PTO/SB/08 a and b being initialed and dated by the Examiner.

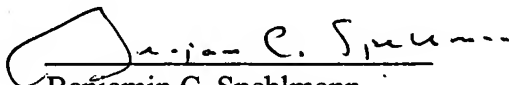
Copies of the non-U.S. patent references are submitted herewith.

These additional references are being provided within the time period specified under 37 C.F.R. § 1.97(b)(3), *i.e.*, before the mailing of a first Office Action on the merits. Therefore, no fee is believed to be due. However, if there is a fee, please debit our Deposit Account No. 19-0733, accordingly.

In accordance with 37 C.F.R. § 1.97(h), the filing of this Supplemental IDS shall not be construed as an admission that the information cited herein is, or is considered to be, material to patentability as defined in 37 C.F.R. § 1.56(b). Applicant does not waive any rights to establish patentability over any of the listed references, should they be applied against the claims of the above-captioned patent application.

Respectfully submitted,

Date: February 16, 2006

By:   
Benjamin C. Spehlmann  
Registration No. 45,649

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**TRANSMITTAL  
FORM**

(to be used for all correspondence after initial filing)

Total Number of Pages in This Submission

Application No.

10/753,078

Filed

January 8, 2004

First Named Inventor

David H. REIFSNYDER

Examiner

Schnizer, Holly G.

Art Unit

1656

Attorney Docket Number

012441.00050 (PP-16331.004)

**ENCLOSURES (check all that apply)**☐ Fee Transmittal Form☐ Fee Attached☐ Amendment / Reply☐ After Final☐ Affidavits/declaration(s)☐ Extension of Time Request☐ Express Abandonment Request☒ Supplemental Information  
Disclosure Statement☐ Certified Copy of Priority  
Document(s)☐ Reply to Missing Parts/  
Incomplete Application☐ Reply to Missing Parts  
under 37 CFR1.52 or 1.53☐ Drawing(s)☐ Licensing-related Papers☐ Petition☐ Petition to Convert to a  
Provisional Application☐ Power of Attorney, Revocation  
Change of Correspondence Address☐ Terminal Disclaimer☐ Request for Refund☐ CD, Number of CD(s) \_\_\_\_\_☐ Landscape Table on CD☐ After Allowance Communication to TC☐ Appeal Communication to Board  
of Appeals and Interferences☐ Appeal Communication to TC  
(Appeal Notice, Brief, Reply Brief)☐ Proprietary Information☐ Status Letter☒ Other Enclosure(s)  
(please identify below):

- 65 References

- International Search Report

**Remarks****SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT**

Firm

Banner &amp; Witcoff, LTD.

Signature

Printed Name

Benjamin C. Spehlmann

Date

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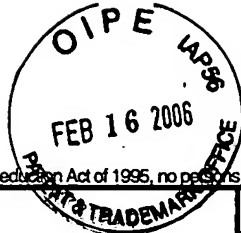
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**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

Sheet 1 of 6

**Complete if Known**

Application Number	10/753,078
Filing Date	January 8, 2004
First Named Inventor	David H. REIFSNYDER
Art Unit	1656
Examiner Name	Schnizer, Holly G.
Attorney Docket Number	012441.00050 (PP-16331.004)

**U.S. PATENT DOCUMENTS**

Examiner Initials *	Cite No. <sup>1</sup>	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number - Kind Code <sup>2</sup> (if known)			
		US- 4,637,834	01-20-1987	Thurrow	
		US- 4,966,852	10-30-1990	Wun et al.	
		US- 5,051,497	09-24-1991	Fanning et al.	
		US- 5,276,015	01-04-1994	Khoury et al.	
		US- 5,358,708	10-25-1994	Patel	
		US- 5,503,827	04-02-1996	Woog et al.	
		US- 5,466,783	11-14-1995	Wun et al.	
		US- 5,563,123	10-08-1996	Innis et al.	
		US- 5,589,359	12-31-1996	Innis et al.	
		US- 5,824,644	10-20-1998	Abendschein	
		US- 5,885,781	01-05-1999	Johnson et al.	
		US- 5,902,582	08-15-1996	Hung	
		US- 6,063,764	05-16-2000	Creasey et al.	
		US- 6,103,500	08-15-2000	Innis et al.	
		US- 6,242,414	06-05-2001	Johnson	

**FOREIGN PATENT DOCUMENTS**

Examiner Initials *	Cite No. <sup>1</sup>	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>6</sup>
		Country Code <sup>3</sup> - Number <sup>4</sup> - Kind Code <sup>5</sup> (if known)				
		EP 0 473 564 A1	03/04/92	Monsanto Co.		
		EP 0 559 632 A2	09/08/93	Monsanto Co.		
		WO 93/25230 A1	12/23/1993	G.D. Searle & Co.		
		WO 93/24143	12/9/1993	Cetus Oncology Corporation		
		WO 96/04378	02/15/1996	Chiron Corporation		
		WO 96/01649	01/25/1996	Washington University		
		WO 96/40224	12/19/1996	Chiron Corporation		
		WO 97/09063	03/13/1997	Chiron Corporation		

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SignatureDate  
Considered

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Sheet	2
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**Complete If Known**

Application Number	10/753,078
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10/753,078

<b>Filing Date</b>	January 8, 2004
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**January 8, 2004**

First Named Inventor	David H. REIFSNYDER
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David H. REIFSNYDER

Art Unit	1656
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1656

Examiner Name	Schnizer, Holly G.
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**Schnizer, Holly G.**

Attorney Docket Number	012441.00050 (PP-16331.004)
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012441.00050 (PP-16331.004)

## U.S. PATENT DOCUMENTS

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## FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>6</sup>
		Country Code <sup>3</sup> - Number <sup>4</sup> - Kind Code <sup>5</sup> (if known)				
		EP 0 414 374 B1	10/08/1997	Smithkline Biologicals S.A.		
		EP 0 755 438 B1	02/14/2001	Amgen Inc.		
		WO 93/18150 A1	09/16/1993	Biocine Sclavo S.P.A.		
		WO 96/01272 A1	01/18/1996	Rican Limited		
		WO 96/01273 A1	01/18/1996	Rican Limited		
		WO 99/57280	11/11/1999	Chiron Corp.		
		WO 01/64922 A2	09/07/2001	Chiron SPA		

Examiner Signature		Date Considered	
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3

of

6

**Complete if Known**

Application Number	10/753,078
Filing Date	January 8, 2004
First Named Inventor	David H. REIFSNYDER
Art Unit	1656
Examiner Name	Schnizer, Holly G.
Attorney Docket Number	012441.00050 (PP-16331.004)

**NON PATENT LITERATURE DOCUMENTS**

Examiner Initials *	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
		Rainer Rudolph, "Successful Protein Folding on an Industrial Scale", Protein Engineering: Principles and Practice, Chapter 10, pps. 283-298 (1996)	
		Rudolph & Lillie, "In Vitro Folding of Inclusion Body Proteins", Folding of Acidic Fibroblast Growth Factor, FASEB J., 10, pps. 49-56	
		Dabora <i>et al.</i> , "Effect of Polyanions on the Refolding of Human Acidic Fibroblast Growth Factor", The Journal of Biological Chemistry, Vol. 266, No. 35, pps. 23637-23640 (1991)	
		Bernhard Fisher <i>et al.</i> , "Isolation, Renaturation, and Formation of Disulfide Bonds of Eukaryotic Proteins Expressed in Escherichia coli as Inclusion Bodies", Biotechnology and Bioengineering, Vol. 41, pps. 3-13 (1993)	
		J. Harenberg, <i>et al.</i> , "Tissue Factor Pathway Inhibitor: Proposed Heparin Recognition Region, Blood Coagulation and Fibrinolysis, Vol. 6, Supp. No. 1, pps. S50-S56 (1995)	
		Mark E. Gustafson <i>et al.</i> , "Renaturation and Purification of Human Tissue Factor Pathway Inhibitor Expressed in Recombinant E. Coli, Protein Expression and Purification", Vol. 5, pps. 233-241 (1994)	
		Carr, C. <i>et al.</i> , "Recombinant E-Coli-Derived Tissue Factor Pathway Inhibitor Reduces Coagulopathic and Lethal Effects in the Baboon Gram-Negative Model of Septic Shock", Wiley-Liss, Div. John Wiley & Sons, Inc., 605 Third Ave., New York, NY 10158-0012	
		Curless <i>et al.</i> , "Phosphate Glass as a Phosphate Source in High Cell Density Escherichia Coli Fermentations", Biotechnology Progress, vol. 12, pp. 22-25 (1996) XP002238061	
		Malaoui <i>et al.</i> , "Influence of Glucose on Glycerol Metabolism by Wild-Type and Mutant Strains of Clostridium Butyricum E5 grown in Chemostat Culture", Applied Microbiology and Biotechnology, vol. 55, December 2000 (2000-12), pp. 226-233, XP002237996	
		Vagabov <i>et al.</i> , "Dependence of Inorganic Polyphosphate Chain Length on the Orthophosphate Content in the Culture Medium of the Yeast Saccharomyces Cerevisiae", Biochemistry (Moscow), vol. 65, 2000, pp. 349-354, XP002237997	

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Considered

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**INFORMATION DISCLOSURE  
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Sheet 4 of 6

**Complete if Known**

Application Number	10/753,078
Filing Date	January 8, 2004
First Named Inventor	David H. REIFSNYDER
Art Unit	1656
Examiner Name	Schnizer, Holly G.
Attorney Docket Number	012441.00050 (PP-16331.004)

**NON PATENT LITERATURE DOCUMENTS**

Examiner Initials *	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
		Albertson <i>et al.</i> , "Growth and Survival of Helicobacter Pylori in Defined Medium and Susceptibility to Brij 78", <i>Journal of Clinical Microbiology</i> , vol. 36, 1998, pp. 1232-1235, XP002238062	
		Bauer <i>et al.</i> , "Improved Expression of Human Interleukin-2 in High-Cell-Density-Density Fermentor Cultures of Escherichia Coli K-12 by a Phosphotransacetylase Mutant", 1990, <i>Appl. Environ. Microbiol.</i> , 56: 1296-1302	
		Bonsignore <i>et al.</i> , "Development of a Chemically Defined Medium for Bacterial Biotin Production", 1989, <i>Abstr. Pap. Am. Chem. Soc.</i> 198 Meet, MBTD 199	
		Box & Wilson, "On the Experimental Attainment of Optimum Conditions", 1951, <i>J. Roy. Statist. Soc.</i> , B13: 1-45	
		Chalmers <i>et al.</i> , "Effects of Temperature on Escherichia Coli Overproducing $\beta$ -Lactamase or Human Epidermal Growth Factor", 1990, <i>Appl. Environ. Microbiol.</i> , 56: 104-111	
		Evans, D.J. <i>et al.</i> , "Identification of Four New Prokaryotic Bacterioferritins, from Helicobacter Pylori, Anabaena Variabilis, Bacillus Subtilis and Treponema Pallidum, by Analysis of Gene Sequences", 1995, <i>Gene</i> , 153: 123-127	
		De Vuyst, L., "Nutritional Factors Affecting Nisin Production by Lactococcus Lactis Subsp. Lactis NIZO 22186 in a Synthetic Medium", 1995, <i>J. Appl. Bacteriol.</i> , 78: 28-33	
		Galindo <i>et al.</i> , "Maximizing the Expression of Recombinant Proteins in Escherichia Coli by Manipulation of Culture Conditions", 1990, <i>J. Ferm. Bioeng.</i> , 69: 159-165	
		Konstantinov <i>et al.</i> , "Physiologically Motivated Strategies for Control of the Fed-Batch Cultivation of Recombinant Escherichia Coli for Phenylalanine Production", 1991, <i>J. Ferm. Bioeng.</i> , 71: 350-355	
		Kopetzki <i>et al.</i> , "Control of Formation of Active Soluble or Inactive Insoluble Baker's Yeast $\alpha$ -Glucosidase PI in Escherichia Coli by Induction and Growth Conditions", 1989, <i>Mol. Gen. Genet.</i> , 216: 149-155	
		Lee & Lee, "Enhanced Production of Poly(3-hydroxybutyrate) by Filamentation-Suppressed Recombinant Escherichia Coli in a Defined Medium", 1996, <i>Journal of Environmental Polymer Degradation</i> , 4(2): 131-134	

Examiner Signature	Date Considered
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Substitute for form 1449B/PTO				<b>Complete if Known</b>	
<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (Use as many sheets as necessary)				Application Number	10/753,078
				Filing Date	January 8, 2004
				First Named Inventor	David H. REIFSNYDER
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Sheet	5	of	6	Attorney Docket Number	012441.00050 (PP-16331.004)

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials *	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
		Luli & Strohl., "Comparison of Growth, Acetate Production, and Acetate Inhibition of Escherichia Coli Strains in Batch and Fed-Batch Fermentations", 1990, <i>Appl. Environ. Microbiol.</i> , 56: 640-645	
		MacDonald & Neway, "Effects of Medium Quality on the Expression of Human Interleukin-2 at High Cell Density in Fermentor Cultures of Escherichia Coli K-12", 1990, <i>Appl. Environ. Microbiol.</i> , 56: 640-645	
		Manetti, R. <i>et al.</i> , "Helicobacter Pylori Cytotoxin: Importance of Native Conformation for Induction of Neutralizing Antibodies", 1995, <i>Infect. Immun.</i> , 63: 4476-4480	
		Okita <i>et al.</i> , "Effect of Induction Temperature on the Production of Malaria Antigens in Recombinant E. Coli", 1989, <i>Biotechnol. Bioeng.</i> , 34: 854-862	
		Park & Ryu, "Effect of Operating Parameters on Specific Production Rate of a Cloned-Gene Product and Performance of Recombinant Fermentation Process" 1990, <i>Biotechnol. Bioeng.</i> , 35: 287-295	
		Rappuoli <i>et al.</i> , "Development of a Vaccine Against Helicobacter Pylori: A Short Overview", 1993, <i>European Journal of Gastroenterology and Hepatology of Helicobacter Pylori Infection</i> , Proceedings of an Interdisciplinary Meeting (Geneva, June 18-19, 1993) J.J. Misiewicz, Ed. (CS Current Science) pp. S76-S78	
		Rappuoli, R., "Toxin Inactivation and antigen Stabilization: Two Different Uses of Formaldehyde", 1994, <i>Vaccine</i> , 12(7): 579-581	
		Rinas <i>et al.</i> , "Glucose as a Ssubstrate in Recombinant Strain Fermentation Technology", 1989, <i>Appl. Microbiol. Biotechnol.</i> , 31: 163-167	
		Stephene, J., "Development and Production Aspects of a Recombinant Yeast-Derived Hepatitis B Vaccine", 1990, <i>Vaccine</i> , 8: S69-S73	

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				Application Number	10/753,078
				Filing Date	January 8, 2004
				First Named Inventor	David H. REIFSNYDER
				Art Unit	1656
				Examiner Name	Schnizer, Holly G.
Sheet	6	of	6	Attorney Docket Number	012441.00050 (PP-16331.004)

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials *	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
		Stratakalaitis <i>et al.</i> , "Development of an Escherichia Coli Culture and Fermentation Process for P <sub>L</sub> -Regulated Expression of HIV-1 Protease," 1991, <i>Abstr. Gen. Meet. Am. Soc. Microbiol.</i> , 91 Meet, 190	
		Zhang <i>et al.</i> , "Process Characterization Studies to Facilitate Validation of a Recombinant Protein Fermentation," 1998, in: Kelley & Ramelmeier (eds) <i>ACS Symposium Ser 698</i> : 12-27	
		Zhang & Greasham, "Chemically Defined Media for Commercial Fermentations," 1999, <i>Appl. Microbiol. Biotechnol.</i> , 51:407-421	
		Moser, A. (1985) Chapters 14-16 of <i>Fundamentals of Biochemical Engineering</i> (ed. Brauer)	
		Carr <i>et al.</i> , <i>Circulatory Shock</i> , 44(3): 126-37 (1994)	
		International Search Report in Counterpart International Application PCT/US04/00234	

Examiner Signature		Date Considered	
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